

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (currently amended) A pharmaceutical composition comprising a mixture of:

(a) an active macromolecular principle; and

(b) a non-conjugated bile acid or salt; and

(c) an additive chosen from ~~propyl gallate, butyl hydroxy anisole (BHA) and analogues and derivatives thereof, or mixtures thereof~~

(i) propyl gallate or a linear or branched chain C₁₋₁₂ alkyl, C₁₋₁₂ alkyloxy, C₁₋₁₂ alkylthio or C₂₋₁₂ alkenyl ester of gallic acid which is optionally

substituted with one or more groups which are the same or different and are selected from halogen and a linear or branched chain C₁₋₁₂ alkyl, C₁₋₁₂ alkyloxy, C₁₋₁₂ alkylthio or C₂₋₁₂ alkenyl ester;

(ii) butyl hydroxy anisole, or butyl hydroxy anisole wherein the methyl group or the methoxy group linked to the aromatic ring and/or the hydrogen ortho to the hydroxyl group is/are replaced by one or more groups which are the same or different and are selected from linear or branched chain C₁₋₁₂ alkyl, C₁₋₁₂ alkyloxy, C₁₋₁₂ alkylthio and C₂₋₁₂ alkenyl, either unsubstituted or substituted in any position by one or more halogen atoms; and

(iii) a mixture of (i) and (ii).

2. (original) A composition according to claim 1, which comprises less than 5% by weight of water.

3. (previously presented) A composition according to claim 1, wherein the composition is coated with an enteric coating which becomes permeable at a pH from 3 to 7.

4. (previously presented) A composition according to claim 1, wherein the mixture comprises at least 1% by weight of the additive (c).

5. (previously presented) A composition according to claim 1, wherein the ratio by weight of the non-conjugated bile salt/additive (b + c) to active macromolecular principle is at least 5:1.

6. (previously presented) A composition according to claim 1, wherein the mixture is in the form of a solution or a microparticulate dispersion.

7. (previously presented) A composition according to claim 1, wherein the mixture is in solid form.

8. (previously presented) A composition according to claim 1, wherein the active macromolecular principle is a polypeptide or protein, polynucleotide, polysaccharide or a mixture thereof.

9. (original) A composition according to claim 8, where the active macromolecular principle is chosen from insulin, calcitonin, growth hormone, parathyroid hormone, or erythropoietin, and derivatives and analogues thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin.

10. (original) A composition according to claim 9, where the active macromolecular principle is insulin, calcitonin, parathyroid hormone or a derivative or analogue thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin.

11. (original) A composition according to claim 10, wherein the active macromolecular principle is insulin or a derivative or analogue thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin, and the composition further comprises an insulin sensitizing agent.

12. (previously presented) A composition according to claim 1, wherein the non- conjugated bile acid or salt is chenodeoxycholate.

13. (previously presented) A composition according to claim 1, wherein the additive is chosen from propyl gallate or an analogue or a derivative thereof, including esters of gallic acid, where the esters may be linear or branched chain C₁₋₁₂ alkyl, C₁₋₁₂ alkyloxy, C₁₋₁₂ alkylthio or C₂₋₁₂ alkenyl esters, and the compounds are optionally substituted with halogen, linear or branched chain C₁₋₁₂ alkyl, C₁₋₁₂ alkyloxy, C₁₋₁₂ alkylthio or C₂₋₁₂ alkenyl esters.

14. (previously presented) A composition according to claim 1, wherein the additive is chosen from BHA or an analogue or derivative thereof, including analogues and derivatives of hydroxy anisole where the methyl group or the methoxy group linked to the aromatic ring and/or the hydrogen ortho to the hydroxyl group are replaced by linear or branched chain C₁₋₁₂ alkyl, C₁₋₁₂

alkyloxy, C₁₋₁₂ alkylthio or C₂₋₁₂ alkenyl, either unsubstituted or substituted in any position, especially by halogen atoms.

15. (previously presented) A composition according to claim 1, for use in the therapeutic or diagnostic treatment of the human or animal body.

16.-17. (canceled).

18. (currently amended) Use A method according to claim 1626, wherein the molecule (s)/active macromolecular principle to be absorbed is a polypeptide or protein, polynucleotide, polysaccharide or a mixture thereof.

19. (currently amended) Use A method according to claim 18 wherein the molecule (s)/active macromolecular principle to be absorbed is chosen from insulin, calcitonin, growth hormone, parathyroid hormone, or erythropoietin, and derivatives and analogues thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin.

20. (currently amended) Use A method according to claim 19, wherein the molecule (s) /active macromolecular principle to be absorbed is insulin, calcitonin, parathyroid hormone or a derivatives or analogue thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin.

21. (currently amended) UseA method according to claim 20, wherein the molecule (s)/active macromolecular principle to be absorbed is insulin or a derivatives or analogue thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin, and an insulin sensitizing agent is also present.

22. (currently amended) UseA method according to claim 1626, wherein the composition comprises less than 5% by weight of water.

23. (currently amended) UseA method according to claim 1626, which comprises incorporating the active macromolecular principle (s) to be absorbed into the aromatic alcohol in the- form of a solution, as a microparticulate dispersion or as a solid.

24. (previously presented) A method of enhancing the absorption of an active macromolecular principle in a patient, which method comprises administering to said patient a composition as defined in claim 1.

25. (previously presented) A method of treating a patient suffering from a condition or disease treatable by administration of a composition according to claim 1.

26. (new) A method of enhancing the absorption of macromolecules across the intestinal wall in a human or animal body, which method comprises administering a non-conjugated bile acid or salt, together with an additive chosen from:

- (i) propyl gallate or a linear or branched chain C₁₋₁₂ alkyl, C₁₋₁₂ alkyloxy, C₁₋₁₂

alkylthio or C₂₋₁₂ alkenyl ester of gallic acid which is optionally substituted with one or more groups which are the same or different and are selected from halogen and a linear or branched chain C₁₋₁₂ alkyl, C₁₋₁₂ alkyloxy, C₁₋₁₂ alkylthio or C₂₋₁₂ alkenyl ester;

- (ii) butyl hydroxy anisole, or butyl hydroxy anisole wherein the methyl group or the methoxy group linked to the aromatic ring and/or the hydrogen *ortho* to the hydroxyl group is/are replaced by one or more groups which are the same or different and are selected from linear or branched chain C₁₋₁₂ alkyl, C₁₋₁₂ alkyloxy, C₁₋₁₂ alkylthio and C₂₋₁₂ alkenyl, either unsubstituted or substituted in any position by one or more halogen atoms; and
- (iii) a mixture of (i) and (ii)

in a pharmaceutical composition.